

## **REMARKS/ARGUMENTS**

Reconsideration of the present application, as amended, is respectfully requested.

### **A. STATUS OF THE CLAIMS**

As result of the present amendment claims 1-15 remain in the case for continued prosecution. No new matter has been added.

### **B. CLAIM INFORMALITIES**

The Examiner has noted informality in claim 11. In response, Applicants have amended the claim to read “sorbitan”, as suggested by the Examiner. In addition, the trademark, Dequest, used in the claim has been removed and specified by its generic term.

### **C. SPECIFICATION**

The Examiner has noted informalities to trademarks used in the specification. In response, Applicants have amended the specification so that the trademarks “Eudragit”, “Kollicoat” and “Dequest” are capitalized and accompanied by their generic terms.

### **D. INDEFINITENESS REJECTIONS**

The Examiner has rejected the subject matter of claims 2, 3, 7, 8, 11, 13 and 15 under 35 USC 112, second paragraph as allegedly being indefinite.

Claims 2, 7, 8 and dependent claim 3 as filed contained trademarks, “Eudragit” and “Kollicoat”. The trademarks included in the claims have been deleted and the claims have been reworded to clarify the generic terms of the deleted trademarks.

Claim 11 has been also amended to delete the trademark, “Dequest”.

Claim 13 has been amended to specify the bases for the percent calculations. Amended claim 13 recites that the percent weights of the components of the tooth-adhering layer are based on “the total dry weight of the tooth-adhering layer” and that the percent weights of the components of the erosion rate-controlling layer are based on “the total dry weight of the erosion rate-controlling layer”. Support can be found, for example, at page 10, lines 22-25, page 11, lines 9-12, page 12, lines 19-21 and page 13, lines 4-6, and claims 4 and 6.

Claim 15, as amended, is dependent on claim 14 which is not indefinite.

Thus, it is respectfully urged that claims 2, 3, 7, 8, 11, 13 and 15 are not indefinite. Reconsideration and removal of the rejections is respectfully requested.

#### **E. THE CLAIMED INVENTION**

The present invention is directed to tooth whitening patches having (i) a tooth adhesion layer and (ii) an erosion rate-controlling layer. The tooth adhesion layer portion includes (a) erodible polymer complexes formed by hydrogen bonding between a carboxyl group-containing polymer and a carbonyl or ether group-containing polymer and (b) a tooth whitening agent. The erosion rate-controlling layer portion includes a mixture of a hydrophilic polymer and a film-forming polymer. The tooth whitening patches are erosion-rate controllable and bioerodible. The erosion rate and the residence time of the tooth whitening patches can be controlled by varying the composition of the erosion rate-controlling layer and also the composition of the adhesion layer. The claimed invention allows the release of the tooth whitening agent in a time-controlled manner and gets rid of the need to remove tooth patches from the mouth after the release of the tooth whitening agent is complete.

#### **F. THE CLAIMS ARE NOT RENDERED OBVIOUS BY THE KIM IN VIEW OF MORO**

##### **1. Summary of the Rejection**

The Examiner has rejected the subject matter of all pending claims under 35 USC 103(a) as allegedly obvious over Kim et al. (WO 01/68045 A1) in view of Moro et al. (U.S. Patent No. 6,585,997). The Examiner has alleged that it would have been obvious to have provided a backing layer on tooth whitening patches of Kim et al. which was erosion rate-controlling and bioerodible by adjusting the type and relative proportions of hydrophilic and hydrophobic polymers used therein, motivated by the desire to provide optimal, tailored delivery of the tooth whitening agent by controlling residence time as taught by Moro et al.

##### **2. 35 USC 103(a) Requirements**

It is urged that the Examiner has not made a proper *prima facie* case of obviousness. Reconsideration and removal of the rejection is therefore proper and earnestly requested. The Examiner is reminded that there must be a motivation to combine and an expectation of success.

A showing of obviousness requires a motivation or suggestion to combine or modify prior art references, coupled with a reasonable expectation of success. The motivation and the expectation of success must be found in the prior art references. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.* 229 F.3d 1120, 56 USPQ2d 1456, (Fed. Cir. 2000) A *prima facie* case of obviousness is thus a showing by the Examiner that the motivation to combine the references and a reasonable expectation of success are found in the prior art references themselves.

### **3. Kim et al. Does Not Disclose Erodible-Controlling and Bioerodible Tooth Whitening Patches**

Kim et al. relates to dry tooth whitening patches having a tooth adhesion layer containing peroxide and a backing layer. The adhesion layer provides a strong adhesion to teeth while releasing the tooth whitening agent when hydrated on the enamel layers of teeth. The backing layer contains water-insoluble and water-impermeable polymers and does not control the residence time of the tooth whitening patches to remain on the teeth.

The Examiner admits on page 6 of the Office Action that Kim et al. does not disclose the erosion rate-controlling layer. (See page 6, lines 5-7). More importantly, the tooth adhesion layer of Kim et al. does not contain the erodible complexes of the carboxyl group-containing polymer and the carbonyl or ether group-containing polymer of the claimed invention.

Unlike Kim et al., the tooth adhesion layer according to the present invention contains the erodible polymer complexes formed by hydrogen bonding of a polymer with a carboxyl group (-COOH) and a polymer with a carbonyl group (-C=O) or ether group (-O-); and a tooth-whitening agent. Hydrogen bonding is contained in the erodible polymer complexes of the tooth-adhesion layer. Solubilization of the erodible polymer complex by saliva in the mouth can be controlled by the type and proportions of the two polymer components in the erodible polymer complexes. That is, the polymer-polymer complex formed by hydrogen bonding can control solubilization of the erodible polymer complex. The cross-linking such as hydrogen bonding is reversible according to solvents, temperature and hydrogen ion concentration, and may control solubility of the polymers in a solution. Also, the binding strength between the polymers varies according to the type of the polymers participating hydrogen bonding and

controls dissolution or erosion rates of the polymers. (See page 11, lines 18-25 and page 9, lines 5-14 of the specification).

The adhesion layer of Kim et al., however, contains a hydrophilic glass polymer merely selected from the specified groups. Kim et al. does not require or intend to contain the erodible complexes formed by hydrogen bonding between the carboxyl group-containing polymer and the carbonyl or ether group-containing polymer.

Accordingly, the present invention is distinguished over Kim et al. primarily because of ① the erosion rate-controlling layer containing a mixture of a hydrophilic polymer and a film-forming polymer and ② the constitution of the tooth adhesion layer.

#### **4. Moro et al. Does Not Suggest or Teach Modifying The Tooth Whitening Patches of Kim et al. To Contain The Erosion Rate-Controlling Layer**

Moro et al. relates to mucosal patches having an adhesive layer and an erodible backing layer. The adhesive layer contains a film-forming hydrophilic polymer and a mucoadhesive polymer and the water-erodible backing layer contains a film-forming hydrophilic polymer and a hydrophobic polymer.

Tooth whitening patches adhere to teeth by a mechanism which is different from that by which transmucosal patches adhere to mucosal tissues. In the tooth whitening patches, the polymers become hydrated by small amount of moisture on teeth. The hydration provides sufficient strength for the tooth patches to remain on teeth. (See page 29, lines 10-15 of the specification) In the transmucosal patches, the polymer chains, however, penetrate into mucosal tissues. At the interface of the polymers and mucosal tissues, mucin released from the mucosal tissues interacts with the polymers, which provides adhesion strength for the transmucosal patches. (See the attached documents, particularly, page 194, right column, lines 2-4 of Article A; page 197, right column, lines 8-9 of Article B; page 1184, right column, lines 4-11 of Article C).

In Moro et al., the water-erodible backing layer controls residence time of the transmucosal patches. Since the transmucosal patches adhere in a fundamentally different way than the tooth whitening patches, Moro et al. does not suggest or teach the use of the tooth whitening patches.

## 5. The Claimed Invention Is Distinguished Over The Tooth Whitening Patches of Kim et al Adapted As Taught By Moro et al

Moro et al. discloses the water-erodible backing layer that controls residence time of the transmucosal patches. Since the tooth whitening patches adhere to teeth by the mechanism different from that of the transmuconal patches, it would not have been obvious to have provided a backing layer in the tooth whitening patches of Kim et al. which was erosion rate-controlling and bioerodible.

Contrary to what the Examiner has contended, even if those skilled in the art modify the tooth whitening patches of Kim et al. as taught by Moro et al., it does not make the claimed invention obvious. The tooth whitening patches of Kim et al. adapted as taught by Moro et al. do not contain the required the erodible complexes of the adhesion layer. The tooth whitening patches of the present invention allow controlling erosion rate and adherence time to the teeth by combination of modifying the type and proportions of the polymer components of the tooth-adhesion layer, and the erosion rate-controlling layer. (See page 26, lines 8-15)

Tables 1-3 of the specification show various combinations of the polymer components and corresponding residence/adherence time. In Examples 1 and 2, the composition of the polymers for the erosion rate-controlling layer was same but the composition of the tooth-adhesion layer varied. The examples show that solubilization of the erodible polymer complexes by saliva in the mouth can be controlled by the type and the proportions of the two polymers in the erodible polymer complexes. (See page 11, lines 18-23). In Examples 4-9, the composition of the polymers for the tooth adhesion layer was same but the composition of the polymers for the erosion rate-controlling layer varied. The examples show that the erosion rate-controlling layer allows controlling the erosion rate of the tooth whitening patches. (See page 13, lines 13-18). Both Kim et al. and Moro et al. do not, however, disclose that the erosion rate and adherence time are also controlled by the tooth-adhesion layer not only by the erosion rate-controlling layer.

The tooth whitening patches of the present invention remains adhered to the teeth surfaces for about 30 min to 3 hrs according to the composition of the two layers and the ratio of the polymers therein, and thereafter gradually eroded until extinguished. (See page 17, line 1-6)

Accordingly, the claimed invention is not obvious over Kim et al. in view of Moro et al. Reconsideration and removal of the rejection is respectfully requested.

**G. FEES**

This response is being filed within a shortened period for response. Thus, no further fee is believed to be required. If, on the other hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

**H. CONCLUSION**

In view of the actions taken and arguments presented, it is respectfully submitted that each and every one of the matters raised by the Examiner have been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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